DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 2, 2015

Bio-Detek, Inc.
% Shannon Duhamel
Regulatory Affairs Specialist
Zoll Medical Corporation
269 Mill Road
Chelmsford, Massachusetts 01824-4105

Re: K150198
Trade/Device Name: CPR Dura-padz Reusable Defibrillation Electrode with Dura-padz Gel
Regulation Number: 21 CFR 870.5310
Regulation Name: Automated External Defibrillator
Regulatory Class: Class III
Product Code: MKJ, LIX
Dated: April 13, 2015
Received: April 14, 2015

Dear Shannon Duhamel,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

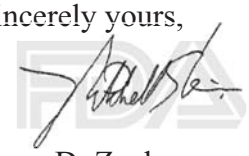
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K150198

Device Name: CPR Dura-padz Reusable Defibrillation Electrode with Dura-padz Gel

Intended Use:

- Defibrillation
- ECG Monitoring
- Cardioversion
- CPR Feedback

The CPR Dura-padz Reusable Defibrillation Electrode is used in conjunction with Dura-padz Gel, and for use with the following ZOLL Biphasic-only defibrillators with max. energy setting of 200 Joules:

- AED Pro
- M Series
- E Series
- R Series

The device will be used in pre-hospital, alternate care and hospital settings by trained personnel only, including:

- Physicians
- Nurses
- Paramedics
- Emergency Medical Technicians
- Cardiovascular Laboratory Technicians
- First Responders

The CPR Dura-padz Reusable Defibrillation Electrodes are not for use with ZOLL AED Plus and/or any Public Access Defibrillators.

The CPR Dura-padz Reusable Defibrillation Electrodes are not indicated for use on a patient less than 8 years of age or weighing less than 55 lbs (25kg).

Prescription Use ___X____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

SECTION 5 – 510(K) SUMMARY

BIO-DETEK
INCORPORATED

510(k) Summary:

Submitter's Name and Address:	Bio-Detek, Inc. 525 Narragansett Park Drive Pawtucket, RI 02861
Application Correspondent:	Shannon Duhamel RA Specialist (978) 421-9574 sduhamel@zoll.com
Date Summary Prepared:	July 9, 2014
Classification:	Class III
Device Name	CPR Dura-padz Reusable Defibrillation Electrode with Dura-padz Gel
Common Name	Automated External Defibrillator Multi-Function Electrodes
Classification Name	Automated External Defibrillators (MKJ; 21 CFR 870.5310) Cardiopulmonary Resuscitation Aid (LIX; 21 CFR 870.5200)
Predicate Devices	K100565 - Dura-padz Reusable Defibrillation Electrode used in conjunction with Dura-padz Gel K110742 - ZOLL OneStep Adult Multi-Function Electrode

Substantial Equivalence – Non-Clinical Evidence:

The existing features and functions (defibrillation, cardioversion and ECG monitoring) of the CPR Dura-padz Reusable Defibrillation Electrode have been cleared per K100565. As with the cleared predicate (K100565), the subject device is intended for use on adult patients with the following ZOLL biphasic-only defibrillators: AED Pro, E Series, R Series and M Series. The CPR Feedback monitoring function is the same technology used in the predicate device cleared per K110742. Safety, efficacy and substantial equivalence was shown through verification and validation testing.

Substantial Equivalence – Clinical Evidence:

N/A – Clinical evidence was not necessary to show substantial equivalence.

Description:

As with the cleared predicate device (K100565), the CPR Dura-padz Reusable Defibrillation Electrode is intended for use with the following ZOLL biphasic-only defibrillators: AED Pro, E Series, R Series and M Series for ECG monitoring, defibrillation and cardioversion. The addition of a CPR sensor (cleared per K110742) to the subject device will enable CPR feedback. As with the currently marketed predicate device (K100565), the CPR Dura-padz electrode is intended for use in conjunction with Dura-padz Gel on adult patients, and the electrode is reusable up to 100 patient uses. The device **Indications For Use** are as follows:

- Defibrillation
- ECG Monitoring
- Cardioversion
- CPR Feedback

The CPR Dura-padz Reusable Defibrillation Electrode is used in conjunction with Dura-padz Gel, and for use with the following ZOLL Biphasic-only defibrillators with max. energy setting of 200 Joules:

- AED Pro
- M Series
- E Series
- R Series

The device will be used in pre-hospital, alternate care and hospital settings by trained personnel only, including:

- Physicians
- Nurses
- Paramedics
- Emergency Medical Technicians
- Cardiovascular Laboratory Technicians
- First Responders

The CPR Dura-padz Reusable Defibrillation Electrodes are not for use with ZOLL AED Plus and/or any Public Access Defibrillators.

The CPR Dura-padz Reusable Defibrillation Electrodes are not indicated for use on a patient less than 8 years of age or weighing less than 55 lbs (25kg).

Comparison of Technological Characteristics:

The CPR Feedback, ECG monitoring, defibrillation and cardioversion functions of the CPR Dura-padz electrode cleared with the predicate devices K110742 and K100565 have remained unchanged in the proposed version of the device.

Performance Testing:

The CPR Dura-padz Reusable Defibrillation Electrode with Dura-padz Gel has been subjected to extensive performance testing to ensure the device meets all of its functional requirements and performance specifications as defined in applicable National/International recognized standards. Performance testing is provided in Section 18 of this submission.

Conclusion:

The information provided in this 510(k) demonstrates that the CPR Dura-padz Reusable Defibrillation Electrode with Dura-padz Gel features and functions are substantially equivalent to those of the indicated commercially distributed devices with regard to performance, safety and effectiveness.